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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,143	11/12/2001	Carol W. Readhead	18810-81609	6154

7590

04/25/2003

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,143

Applicant(s)

Readhead et al.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 12, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 135-145 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 135-145 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

This application filed November 12, 2001, is a divisional of application 09/191,920, filed November 13, 1998, now US Patent 6,316,692, which claims benefit to provisional application 60/065,825, filed November 14, 1997.

Applicants preliminary amendment filed November 12, 2001, paper number 2, has been received and entered. The specification has been amended. Claims 1-134 have been canceled. Claims 135-145 have been added.

Claims 135-145 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 135-139, 143-145, drawn to a kit comprising: (1) a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker, classified in class 536, subclass 23.1, 23.4, 24.1, and class 435, subclass 93.1.
- II. Claim 140, drawn to a kit comprising: (1) a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker, which further comprises (4) a c-kit ligand, classified in class 536, subclass 23.1, 23.4,

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24.1, and class 435, subclass 93.1, and class 530, subclass 350 (for additional ligand).

- III. Claims 141-142, drawn to a kit comprising: (1) a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker, which further comprises (4) an immunosuppressing agent, classified in class 536, subclass 23.1, 23.4, 24.1, and class 435, subclass 93.1, and additional classes depending on the specific type of immunosuppressing agent.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed. The number of specific components of the kit recited in claim 135 is smaller than those set forth in dependent claims, however because of the open language the kit of claim 135 can comprise many more components and is thus considered the combination. The inventions are distinct because the components set forth in claim 135 can be used by itself and does not require, for example, the further addition of the other particular components set forth in dependent claims. The subcombination has separate utility in that the kits comprise different components

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which would be used in particular circumstances. For example, the c-kit ligand could be used to target a cell, to activate cells, or to block the receptor when using the other components of the kit, and the addition of an immunosuppressant would be used in circumstances when the agents being delivered were foreign or particularly antigenic. Additionally, it is noted that while the preamble of the claim indicates that the components of the kit are provided for transfecting vertebrate germ cells, the kit and the components can be used for other purposes.

Inventions II and III are related as subcombinations. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each of the further components of the inventions have separate utility because they are provided separately and individually, and provide for a materially different product. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required and different from that for Groups II-III, restriction for examination purposes as indicated is proper.

In addition, if any group is elected an additional election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: claims 136-139 recite specific species of transfecting agents. Each of the species are directed to structurally different types of transfecting agents. One transfecting agent must be

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elected from the group of a(n): (1) liposome, (2)-(7) specific viral vectors listed in claim 137, (8) adenovirus vector having endosomal lytic activity, (9) transferrin-polylysine enhanced vectors, (10) uptake enhancing DNA segments, (11) lipid or any specific combination of a mixture of these species set forth (for example-a combination of (1) a liposome and (5) a HIV vector). Only one specific species or combination of species of transfecting agents listed above must be indicated in the election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 135, 143, 144 and 145 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

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Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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